

NOTICE OF PROPOSED RULE

TYPE OF RULE: Amendment

Rule or Section Number:

R68-28

Filing ID: 55343

Agency Information

1. Department:	Agriculture and Food	
Agency:	Plant Industry	
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Please address questions regarding information on this notice to the agency.		

General Information

2. Rule or section catchline:
R68-28. Cannabis Processing
3. Purpose of the new rule or reason for the change (Why is the agency submitting this filing?):
Changes are needed to add clarifications to this rule related to definitions and labeling requirements. Additionally, changes are needed to make this rule consistent with the statute following changes passed during the 2023 General Session in S.B. 91.
4. Summary of the new rule or change (What does this filing do? If this is a repeal and reenact, explain the substantive differences between the repealed rule and the reenacted rule):
Changes have been made to the definition section to clarify existing definitions and add a definition for artificially derived cannabinoid, consistent with statutory changes.
In Section R68-28-4, language has been added to add record keeping requirements for vaporizer cartridge heavy metal testing, also now required in statute following the passage of S.B. 91 (2023).
In Section R68-28-7, language has been added addressing the ability of cannabis processors to purchase cannabinoid isolate from industrial hemp processors. This will replace the purchase of industrial hemp waste that is no longer allowed statutorily.
Clarifying inventory information requirements are added to Section R68-28-8 and agent clarifications are added to Section R68-28-9 to address the statutory change of agent cards being issued to individuals rather than cannabis production establishments.
Finally in Section R68-28-13, clarifications are added regarding labeling requirements based on the Department of Agriculture and Food's (Department) needs to manage the program. Additionally, warning requirements are added consistent with statutory changes.

Fiscal Information

5. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:
A) State budget:
There will be some saved costs to the Department because the Department no longer will be approving hemp waste transfers; however, there will be increased costs for inspecting cannabinoid isolate records. Overall, there should be no fiscal impact to the Department with these changes.
B) Local governments:
Local governments will not be impacted because they do not participate as or regulate medical cannabis processors.
C) Small businesses ("small business" means a business employing 1-49 persons):

Small businesses will experience a fiscal cost related to adhering to new labeling requirements. The Department estimates this will be approximately \$3,000 per processor, or a total of \$45,000 split evenly between small and non-small businesses or \$22,500 each in FY 2024 only.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

Small businesses will experience a fiscal cost related to adhering to new labeling requirements. The Department estimates this will be approximately \$3,000 per processor, or a total of \$45,000 split evenly between small and non-small businesses or \$22,500 each in FY 2024 only.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an **agency**):

Other persons will not be impacted by the changes because they are not medical cannabis licensees and do not regulate medical cannabis processing.

F) Compliance costs for affected persons (How much will it cost an impacted entity to adhere to this rule or its changes?):

Compliance costs for affected persons will not change aside from the increased cost for labeling of approximately \$3,000 per cannabis processor.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

Fiscal Cost	FY2023	FY2024	FY2025
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$22,500	\$0
Non-Small Businesses	\$0	\$22,500	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$45,000	\$0
Fiscal Benefits	FY2023	FY2024	FY2025
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$(45,000)	\$0

H) Department head comments on fiscal impact and approval of regulatory impact analysis:

The Commissioner of the Department of Agriculture and Food, Craig W Buttars, has reviewed and approved this regulatory impact analysis.

Citation Information

6. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:

Subsection 4-41a-103(5)

Public Notice Information

8. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until: 06/14/2023

9. This rule change MAY become effective on: 06/21/2023

NOTE: The date above is the date the agency anticipates making the rule or its changes effective. It is NOT the effective date.

Agency Authorization Information

Agency head or designee and title:	Craig W Buttars, Commissioner	Date:	04/18/2023
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R68-28-1. Authority and Purpose.

(1) Pursuant to Subsections 4-41a-103(5), 4-41a-302(3)(b)(ii), 4-41a-404(3), 4-41a-405(2)(b)(iv), 4-41a-701(3), 4-41a-801(1), and 4-2-103(1)(i), this rule establishes the application process, qualifications, and requirements to obtain and maintain a cannabis processing license.

R68-28-2. Definitions.

- (1) "Appealing to children" means:
- (a) has a likeness bearing resemblance to a cartoon character or fictional character; or
 - (b) appears to imitate a food or other product that is typically marketed toward or is appealing to children.
- (2) "Applicant" means any person or business entity who applies for a cannabis processing facility license.
- (3)(a) "Artificially derived cannabinoid" means a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from the cannabis plant.
- ~~(b) "Artificially derived cannabinoid" does not include:~~
- ~~(i) a naturally occurring chemical substance that is separated from the cannabis plant by a chemical or mechanical extraction process; or~~
 - ~~(ii) a cannabinoid that is produced by decarboxylation from a naturally occurring cannabinoid acid without the use of a chemical catalyst.~~
- ~~([3]4) "Batch" means a quantity of:~~
- (a) cannabis extract produced on a particular date and time, following clean up until the next clean up during which lots of cannabis are used;
 - (b) cannabis product produced on a particular date and time, following clean up until the next clean up during which cannabis extract is used; or
 - (c) cannabis flower packaged on a particular date and time, following clean up until the next clean up during which lots of cannabis are being used.
- ~~(5) "Brand name" means a type of product manufactured by a particular company under a particular name. "Brand name" does not mean strains or flavors.~~
- ~~([4]6) "Board" means the Cannabis Production Establishment Licensing Advisory Board, created in Section 4-41a-201.1.~~
- ~~(7) "Cannabinoid isolate" means the same as the term is defined in Subsection R68-29-2(11).~~
- ~~([5]8)(a) "Cannabis" means any part of a marijuana plant.~~
- ~~(b) "Cannabis" does not mean, for the purposes of this rule, industrial hemp.~~
- ~~([6]9) "Cannabis concentrate" means the product of any chemical or physical process applied to cannabis biomass that concentrates or isolates the cannabinoids contained in the biomass.~~
- ~~([7]10) "Cannabis cultivation byproduct" means any portion of a cannabis plant that is not intended to be sold as a cannabis plant product.~~
- ~~([8]11) "Cannabis cultivation facility" means a person that:~~
- ~~(a) possesses cannabis;~~
 - ~~(b) grows or intends to grow cannabis; and~~
 - ~~(c) sells or intends to sell cannabis to a cannabis cultivation facility or to a cannabis processing facility.~~
- ~~([9]12) "Cannabis derivative product" means a product made using cannabis concentrate.~~
- ~~(1[0]3) "Cannabis fact panel" means a part of the label that contains the information described in Subsections R68-28-13(6) and R68-28-13(7).~~
- ~~(1[1]4) "Cannabis plant product" means any portion of a cannabis plant intended to be sold by a medical cannabis pharmacy in a form that is recognizable as a portion of a cannabis plant.~~
- ~~(1[2]5) "Cannabis processing facility" means a person that:~~
- ~~(a) acquires or intends to acquire cannabis from a cannabis production establishment;~~
 - ~~(b) possesses cannabis with the intent to manufacture a cannabis product;~~
 - ~~(c) manufactures or intends to manufacture a cannabis product from unprocessed cannabis or a cannabis concentrate; and~~
 - ~~(d) sells or intends to sell a cannabis product to a medical cannabis pharmacy.~~
- ~~(1[3]6) "Cannabis processing facility agent" means an individual who[:]~~
- ~~a) is an employee of a cannabis processing facility; and~~
 - ~~b) holds a valid cannabis production establishment agent registration card[.] with a cannabis processing facility designation.~~
- ~~(1[4]7) "Cannabis production establishment agent registration card" means a registration card that the department issues that:~~
- ~~(a) authorizes an individual to act as a cannabis production establishment agent; and~~
 - ~~(b) designates the type of cannabis production establishment for which an individual may act as an agent.~~
- ~~(1[5]8) "COA" means Certificate of Analysis from an independent cannabis testing laboratory.~~
- ~~(1[6]9) "Complaint" means any negative feedback received from a medical cannabis patient or medical cannabis or industrial hemp licensee.~~
- ~~([17]20) "Department" means the Utah Department of Agriculture and Food.~~
- ~~(21) "Directions for use" means recommended routes of administration for a medical cannabis treatment and suggested usage guidelines, and may include:~~
- ~~(a) THC percentage;~~
 - ~~(b) strain names;~~
 - ~~(c) strain dominance; or~~
 - ~~(d) dietary restrictions.~~
- ~~([18]22) "Label" means a written, printed, or graphic display on the immediate container of a product.~~
- ~~([19]23) "Labeling" means a label and other written, printed, or graphic display:~~
- ~~(a) on the product or the product's container or wrapper; or~~
 - ~~(b) accompanying the product.~~
- ~~(24) "Logo" means symbols, stylized text, or both that represent a company through a visual image that can be easily understood and recognized.~~
- ~~(2[0]5) "Lot" means the quantity of:~~
- ~~(a) flower produced on a particular date and time, following clean up until the next clean up during which the same materials are used; or~~

(b) trim, leaves, or other plant matter from cannabis plants produced on a particular date and time, following clean up until the next clean up.

(2[4]6) "Product face" means the part of a label that is on the outer packaging and most likely to be displayed, presented, or shown under customary conditions of display for retail sale.

(2[2]7) "Total THC" means the sum of the determined amounts of delta-9-THC and delta-9-THCA, according to the formula: Total THC = delta-9-THC + (delta-9-THCA x 0.877).

R68-28-3. Cannabis Processing Facility License.

(1) A cannabis processing facility license allows the licensee to receive cannabis from a cannabis production facility.

(2) A Tier 1 cannabis processing facility license allows the licensee to:

- (a) create cannabis concentrate;
- (b) create cannabis derivative product; and
- (c) package and label final product.

(3) A Tier 2 cannabis processing facility license allows the licensee to package and label cannabis and cannabis final product.

(4) A complete application shall include the required fee, statements, forms, diagrams, operation plans, copy of current Utah manufactured food establishment registration, and other applicable documents required in the application packet to be accepted and processed by the department.

(5) Before approving an application, the department may contact the applicant and request additional supporting documentation or information.

(6) Before issuing a license, the department shall inspect the proposed premises to determine if the applicant complies with state laws and rules.

(7) Each cannabis processing facility license shall expire one calendar year from the date of licensure.

(8) An application for renewals shall be submitted to the department 30 days before expiration.

(9) If the renewal application is not submitted 30 days before the expiration date, the licensee may not continue to operate.

(10) A cannabis production establishment license is not transferable or assignable. If the ownership of a cannabis production establishment changes by 50% or more, the requirements of Subsection 4-41a-201(15) shall be followed.

R68-28-4. Cannabis Processing Facility Requirements.

(1) A cannabis processing facility operating plan shall contain a blueprint of the facility containing the following information:

- (a) the square footage of the areas where cannabis is to be extracted;
- (b) the square footage of the areas where cannabis or cannabis products are to be packaged and labeled;
- (c) the square footage of the areas where cannabis products are manufactured;
- (d) the square footage and location of storerooms for cannabis awaiting extraction;
- (e) the square footage and location of storerooms for cannabis awaiting further manufacturing;
- (f) the area where finished cannabis and cannabis products are stored;
- (g) the location of toilet facilities and hand washing facilities;
- (h) the location of a break room and location of personal belonging lockers;
- (i) the location of the areas to be used for loading and unloading of cannabis and cannabis products; and
- (j) the total square footage of the overall cannabis processing facility.

(2) A cannabis processing facility shall have written emergency procedures to be followed in case of:

- (a) fire;
- (b) chemical spill; or
- (c) other emergency at the facility.

(3) A cannabis processing facility shall have a written plan to handle potential recall and destruction of cannabis due to contamination.

(4) A cannabis processing facility shall use a standardized scale that is registered with the department when cannabis is:

- (a) packaged for sale by weight;
- (b) bought and sold by weight; or
- (c) weighed for entry into the inventory control system.

(5) A cannabis processing facility shall compartmentalize each area in the facility based on function and shall limit access between compartments.

(6) A cannabis processing facility shall limit access to the compartments to the appropriate agents.

(7) A cannabis processing facility creating cannabis derivative product shall develop standard operating procedures.

(8) Pursuant to Subsection 4-41a-403(4)(b), a cannabis processing facility may use signage on the property that includes a logo, as long as the logo does not include:

- (a) unprofessional terms, slang, phrasing, or verbiage associated with the recreational use of cannabis;
- (b) any image bearing resemblance to a cartoon character or fictional character whose target audience is children or minors;
- (c) content, symbol, or imagery that the cannabis processing facility knows or should know appeals to children;
- (d) imagery featuring a person using the product in any way;
- (e) any recreationally oriented subject; or
- (f) any statement, design, or representation, picture, or illustration that is obscene or indecent.

(9) A cannabis processing facility shall keep records of any complaints received and make those records available to the department upon request.

(10) A cannabis processing facility shall keep records verifying that each time they receive a batch of vaporizer cartridges a sample is tested for heavy metals by an independent cannabis testing laboratory pursuant to Section 4-41a-603.

R68-28-5. Separation of Cannabis and Hemp Processed in a Single Facility.

(1) Any facility that has both an industrial hemp processing license and a license for medical cannabis processing shall ensure physical separation of medical cannabis and industrial hemp in their facility.

(2) Processing of industrial hemp material and cannabis material shall not occur on the same equipment on the same day, unless cleaned between runs.

- (3) Processing equipment may be considered neutral territory for hemp and cannabis if:
 - (a) only one material is present in neutral territory at a time;
 - (b) packaging tables in neutral territory are only used for the material being processed that day; and
 - (c) if packaging tables are used for another material they shall be moved to the respective side of the facility.
- (4) If the facility uses the same machinery to process both industrial hemp and medical cannabis:
 - (a) the machinery shall be cleaned in between hemp and cannabis days;
 - (b) cleaning logs shall be kept and monitored by the department upon inspection of the facility; and
 - (c) cleaning logs shall include the machines used, the date cleaned, and the name of the employee that conducted the cleaning.
- (5) Packaging of medical cannabis and industrial hemp may occur:
 - (a) in a neutral zone; or
 - (b) in a designated side of the facility.
- (6) Freezer separation.
 - (a) Each licensee that processes both medical cannabis and industrial hemp shall have a separate freezer or a physical separation within the same freezer for each material.
 - (b) Cannabis and hemp material shall be clearly labeled pursuant to the requirements of this rule and Rule R68-25 and shall be in sealed containers.
- (7) Storage separation.
 - (a) Industrial hemp and medical cannabis shall be stored in separate secure locations.
 - (b) Storage shall include storage for:
 - (i) final product;
 - (ii) raw material; and
 - (iii) processed material.
- (8) Upon request, the licensee shall inform the department of how separation of materials is implemented, including the facility's separation procedures for raw material, extract, and final products.

R68-28-6. Cannabis Extraction Requirements.

- (1) A cannabis processing facility shall ensure hydrocarbons n-butane, isobutane, propane, or heptane are of at least 99% purity.
- (2) A cannabis processing facility shall use a professional grade ~~closed-loop~~ extraction system designed to recover the solvents, work in an environment with proper ventilation, and control each source of ignition where a flammable atmosphere is or may be present.
- (3) A cannabis processing facility using carbon dioxide (CO₂) gas extraction system shall use a professional grade closed loop CO₂ gas extraction system where each vessel is rated to a minimum of six hundred pounds per square inch and CO₂ shall be at least 99% purity.
- (4) Closed loop hydrocarbon, alcohol, or CO₂ extraction systems shall be commercially manufactured and bear a permanently affixed and visible serial number.
- (5) A cannabis processing facility using a closed loop system shall, upon request, provide the department with certification from a licensed engineer stating the system is:
 - (a) safe for its intended use;
 - (b) commercially manufactured; and
 - (c) built to conform to recognized and generally accepted good engineering practices, such as:
 - (i) the American Society of Mechanical Engineers (ASME);
 - (ii) American National Standards Institute (ANSI);
 - (iii) Underwriters Laboratories; or
 - (iv) The American Society for Testing and Materials.
- (6) The certification document shall contain the signature and stamp of the certifying professional engineer and the serial number of the extraction unit being certified.
- (7) A cannabis processing facility may use an alternative extraction method with prior approval from the department.
- (8) A cannabis processing facility shall use food grade ingredients to create cannabis derivative product.
- (9) A cannabis processing facility may use heat, screens, presses, steam distillation, ice water, and other mechanical methods which do not use solvents or gasses.
- (10) A cannabis processing facility shall ensure each solvent, with the exception of CO₂, is extracted in a manner to recapture the solvent and ensure that it is not vented into the atmosphere.
- (11) A cannabis ~~establishment~~ processing facility agent using solvents or gasses in a closed loop system shall be fully trained in the use of the system and have direct access to applicable material safety data sheets.
- (12) Parts per million for one gram of finished extract cannot exceed residual solvent or gas levels provided in Rule R68-29.

R68-28-7. Cannabinoid Isolate.

- (1) A licensed Tier 1 cannabis processing facility may use cannabinoid isolate from a licensed industrial hemp processing facility.
- (2) A Tier 1 cannabis processing facility may not receive more than 120 kilograms of cannabinoid isolate in a single license year.
- (3) Any transfer of cannabinoid isolate shall be accompanied by a full panel COA.
- (4) The cannabis processing facility shall maintain record of each transfer of cannabinoid isolate that is available for review by the department, including:
 - (a) the source of the cannabinoid isolate and verification that it was derived from certified industrial hemp;
 - (b) the intended use of the cannabinoid isolate; and
 - (c) the disposition of the cannabinoid isolate.
- (5) Upon receipt of cannabinoid isolate, a cannabinoid processing facility shall submit a sample of the isolate to a licensed independent cannabis testing laboratory for cannabinoid and adulterant testing, pursuant to the requirements of Rule R68-29.

R68-28-[7]8. Security Requirements.

- (1) At a minimum, each cannabis processing facility shall have a security alarm system on each perimeter entry point and perimeter window.

- (2) At a minimum, a licensed cannabis processing facility shall have a complete video surveillance system:
- (a) with minimum camera resolution of 1280 x 720 pixels or pixel equivalent for analog; and
 - (b) that retains footage for at least 45 days.
- (3) Each camera shall be fixed and placement shall allow for the clear and certain identification of any person and activities in controlled areas.
- (4) Controlled areas included:
- (a) any entrances and exits, or ingress and egress vantage points;
 - (b) any areas where cannabis or cannabis products are stored;
 - (c) any areas where cannabis or cannabis products are extracted;
 - (d) any areas where cannabis or cannabis products are manufactured, packaged, or labeled; and
 - (e) any areas where cannabis waste is being moved, processed, stored, or destroyed.
- (5) Each camera shall record continuously.
- (6) For locally stored footage, the surveillance system storage device shall be secured in the facility in a lockbox, cabinet, closet, or secured in another manner to protect from employee tampering or theft.
- (7) For footage stored on a remote server, access shall be restricted to protect from employee tampering.
- (8) Any gate or entry point must have lighting sufficient to record activity occurring in low light conditions.
- (9) Each visitor to a cannabis processing facility shall be required to display an identification badge issued by the facility while on the premises.
- (10) At any time, visitors shall be escorted by a cannabis processing facility agent.
- (11) A cannabis processing facility shall keep and maintain a visitors log showing:
- (a) the full name of each visitor entering the facility;
 - (b) badge number issued;
 - (c) the time of arrival;
 - (d) the time of departure; and
 - (e) the purpose of the visit.
- (12) The cannabis processing facility shall keep the visitors log for a minimum of one year.
- (13) The cannabis processing facility shall make the visitor log available to the department upon request.

R68-28-[8]9. Inventory Control.

(1) Each batch or lot of cannabis, cannabis derivative product, cannabis product, test sample, or cannabis waste shall be entered into~~have a unique identifier in~~ the inventory control system. Recorded information shall include:

- (a) unique identification number;
- (b) package ID;
- (c) name of product;
- (d) facility name and license number; and
- (e) date created.

- (2) Each batch or lot of cannabis, cannabis derivative product, cannabis product, sample, or cannabis waste shall be traceable to the lot.
- (3) Unique identification numbers may not be reused.
- (4) Each batch, lot, or sample of cannabis shall have a unique identification number that is displayed on a physical tag.
- (5) The tag shall be legible and placed in a position that can be clearly read.
- (6) The following shall be reconciled in the inventory control system at the close of each business each day:
- (a) date and time material containing cannabis are being transported to a cannabis production establishment or medical cannabis pharmacy;
 - (b) each sample used for testing and the test results;
 - (c) a complete inventory of material containing cannabis;
 - (d) cannabis product by unit count;
 - (e) weight per unit of product;
 - (f) weight and disposal of cannabis waste materials;
 - (g) the identity of who disposed of the cannabis waste and the location of the waste receptacles; and
 - (h) theft or loss or suspected theft or loss of material containing cannabis.
- (7) A receiving cannabis processing facility shall document in the inventory control system any material containing cannabis received, and any difference between the quantity specified in the transport manifest and the quantity received.
- (8) A cannabis processing facility shall immediately upon receipt of THC extract from a licensed industrial hemp processor enter the following information into the inventory control system:
- (a) the amount of THC extract received;
 - (b) the name, address, and licensing number of the industrial hemp processor;
 - (c) the weight per unit of product received; and
 - (d) the assigned unique identification number.

R68-28-[9]10. Cannabis Processing Facility Agents.

- (1) A prospective cannabis processing facility agent shall apply to the department for a cannabis ~~establishment~~ processing facility agent registration card on a form provided by the department.
- (2) An application is not considered complete until the background check has been completed, ~~and~~ ~~the~~ ~~facility has paid~~ the registration fee has been paid, and the prospective agent has submitted the required training certificate.
- (3) The cannabis processing facility agent registration card shall contain:
- (a) the full name of the agent;
 - ~~(b) the name of the cannabis processing establishment;~~
 - ~~(e)~~ ~~b~~ ~~the job title or position of the agent~~ identifying information; and
 - ~~(d)~~ ~~c~~ a photograph of the agent.
- (4) A cannabis processing facility is responsible to ensure that each agent has received~~;~~

~~_____ a) the department approved training as specified in Section 4-41a-301; and~~

~~_____ b) any task specific training as outlined in the operating plan submitted to the department.~~

(5) A cannabis processing facility agent shall have a properly displayed identification badge which has been issued by the department at all times while on the facility premises or while engaged in the transportation of cannabis.

(6) Each cannabis ~~[production establishment]~~ processing facility agent shall have their state issued identification card in their possession to certify the information on their badge is correct.

~~_____ 7) Upon termination, the identification badge of an agent shall be immediately returned to the department by the cannabis processing facility.~~

(7) Each cannabis processing facility shall maintain a list of each employee that holds a cannabis processing facility agent registration card and provide the list to the department upon request.

R68-28-1[0]1. Minimum Storage and Handling Requirements.

(1) A cannabis processing facility shall store cannabis, cannabis concentrate, or cannabis product in a ~~[separate-]~~ location separated by a physical barrier from outdated, damaged, deteriorated, misbranded, or adulterated product or product whose containers or packaging have been opened or breached.

(2) Cannabis, cannabis concentrate, and cannabis product shall be stored at least six inches off the ground.

(3) Storage areas shall:

(a) be maintained in a clean and orderly condition; and

(b) be free from infestation by insects, rodents, birds, or vermin.

(4) A cannabis processing facility shall:

(a) track and label each cannabis plant product and cannabis concentrate;

(b) ensure each unfinished product is stored in a secure location; and

(c) immediately after completion of the process or at the end of the scheduled business day return to a secure location.

(5) Cannabis shall be stored away from other chemicals, lubricants, pesticides, or other potential contaminants.

(6) If a manufacturing process cannot be completed at the end of a working day, the processor shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing cannabis inside an area or room that affords adequate security.

R68-28-1[1]2. Product Appearance and Flavor.

(1) A cannabis processing facility may not produce a cannabis product that is designed to mimic a candy product.

(2) A cannabis processing facility may not shape a cannabis product in any way to appeal to children.

R68-28-1[2]3. Processing of Cannabis and Cannabis Product.

(1) A cannabis processing facility shall process, manufacture, package, and label cannabis and cannabis product in accordance with 21 CFR 111, "Current Good Manufacturing, Packaging, Labeling, or Holding Operation for Dietary Supplements."

(2) Cannabis and cannabis product shall be packaged in child-resistant packaging in accordance with 16 CFR 1700.

(3) A cannabis processing facility shall package cannabis or cannabis product in accordance with this rule and Section 4-41a-602 before transportation to a medical cannabis pharmacy.

(4) Any container or packaging containing cannabis or cannabis product shall protect the product from contamination and shall not impart any toxic or deleterious substance to the cannabis or cannabis product.

(5) Cannabis cultivation byproduct shall either be:

(a) chemically or physically processed to produce a cannabis concentrate for incorporation into cannabis derivative product; or

(b) destroyed according to Section 4-41a-405.

(6) Cannabis concentrate and product produced by cannabis processing facilities shall be tested pursuant to Rule R68-29.

(7) If a cannabis product contains ~~[derivative or synthetic]~~ artificially derived cannabinoids they shall be isolated to a purity of greater than 95%, as required by Subsection 4-41a-603(3).

(8) A cannabis product may vary in the cannabis product's labeled cannabinoid profile by up to 10% of the indicated amount of a given cannabinoid, by weight.

R68-28-1[3]4. Labeling and Packaging of Cannabis and Cannabis Product.

(1) Cannabis product labeling shall contain the following information:

(a) ~~[the common or usual name of the product;]~~ the medicinal dosage form identified on the product face along with the words "THC or Cannabis Infused":

~~_____ (i) "gummies" may be used instead of "gelatinous cube";~~

~~_____ (ii) "tincture" may be used instead of "sublingual preparation" or "liquid suspension"; and~~

~~_____ (iii) a descriptive product name is allowed if the text is smaller than the dosage form and is no appealing to children;~~

(b) the name and license number of the cannabis processing facility;

(c) directions for consumers to contact the department with product complaints by going to medicalcannabis.utah.gov/production;

(d) for products containing THC, a warning symbol provided by the department; and

(e) the amount of total THC contained in the package, in milligrams. ~~[; and]~~

~~_____ ([#]2) Before January 1, 2024, cannabis product labeling shall contain the following warning: "WARNING: Cannabis has intoxicating effects and may be addictive. Do not operate a vehicle or machinery under its influence. KEEP OUT OF REACH OF CHILDREN. This product is for medical use only. Use only as directed by a recommending medical provider."~~

(3) Starting on January 1, 2024, cannabis product labeling shall contain the following warning: "WARNING: Cannabis has intoxicating effects, may be addictive, and may increase risk of mental illness. Do not operate a vehicle or machinery under its influence. KEEP OUT OF REACH OF CHILDREN. This product is for medical use only. Use only as directed by a recommending medical provider."

(4) Starting on May 3, 2023, raw cannabis or a cannabis product sold in a vaporizer cartridge shall include a warning label that states:

(a) "WARNING: Vaping of cannabis-derived products has been associated with lung injury."; and

(b) "WARNING: Inhalation of cannabis smoke has been associated with lung injury."

~~(2)5~~ A cannabis processing facility may include a QR code on the cannabis product labeling that ~~contains a~~ links to a COA from a licensed independent cannabis testing laboratory. The QR code may not link to any other information.

~~(3)6~~ Any information appearing on the cannabis product labeling shall be:

(a) displayed in any legible font, that is not a script or decorative font, provided that the lowercase letter "o" is at least one-sixteenth inch in height;

(b) displayed in a color that contrasts conspicuously with its background; and

(c) displayed in English, although a licensee may also choose to display required information in additional languages.

~~(4)7~~ A cannabis processing facility shall place a cannabis fact panel on a cannabis product before the sale of the cannabis product to a medical cannabis pharmacy.

~~(5)8~~ The cannabis fact panel shall be printed in black and white.

~~(6)9~~ The cannabis fact panel shall be securely affixed to the package.

~~(7)10~~ The cannabis fact panel for cannabis plant product shall include the following information, from top to bottom, in the order as listed:

(a) the name of the cannabis cultivation facility;

(b) the lot number;

(c) the date of harvest;

(d) the date of final testing;

(e) the batch number;

(f) the date on which the product was packaged;

(g) the quantity of any cannabinoid listed as present on the COA that is greater than 1% of total cannabinoids;

(h) the expiration date; and

(i) the net weight displayed in grams.

~~(8)11~~ THC potency levels for cannabis flower shall be listed as total THC in milligrams per gram.

~~(9)12~~ The cannabis fact panel for cannabis derivative product shall include the following information, from top to bottom, in the order listed:

(a) the batch number;

(b) the date of the final testing;

(c) the date on which the product was packaged;

(d) the quantity of any cannabinoid listed as present on the COA that is greater than 1% of total cannabinoids;

(e) the expiration date;

(f) the total amount of THC measured in milligrams per gram;

(g) a list of each ingredient and each major food allergen as identified in 21 U.S.C. 343;

(h) the identity ~~and quantity~~ of any ~~derivative or synthetic~~ artificially derived cannabinoid present in the product;

(i) the net weight of the product displayed in grams or milliliters and number of pieces, if applicable; and

(j) a disclosure of the type of extraction process used and any solvent, gas, or other chemical used in the extraction process.

~~(10)3~~ The label of a cannabis derivative product may include a flavor name if it is not candy-like or a name the facility knows or should know appeals to children.

~~(11)4~~ The label of a cannabis product that contains ~~a derivative or synthetic~~ an artificially derived cannabinoid shall clearly display the following text: "This product contains ~~derivative or synthetic~~ artificially derived cannabinoids."

~~(12)5~~ Any terpene listed on a cannabis product package shall be verified as present by a licensed independent cannabis testing laboratory and have its quantity listed on the fact panel.

~~(13)6~~ A cannabis processing facility may include ~~a~~ the licensee's logo and product brand name on the cannabis product ~~label~~ face that is exempt from the requirements of Subsection R68-28-13(3) and that:

(a) does not exceed 20% of the product face;

(b) does not obscure the information required on the label; and

(c) does not include:

(i) unprofessional terms, slang, phrasing, or verbiage associated with the recreational use of cannabis;

(ii) any image bearing resemblance to a cartoon character or fictional character whose target audience is children or minors;

(iii) content, symbol, or imagery that the cannabis processing facility knows or should know appeals to children;

(iv) imagery featuring a person using the product in any way;

(v) any recreationally oriented subject; or

(vi) any statement, design, or representation, picture, or illustration that is obscene or indecent.

~~(14)7~~ No other information, illustration, or depiction with the exception of directions for use shall appear on the labeling.

~~(15)8~~ Shapes on cannabis product packaging or labeling shall not resemble the product or real-world items.

~~(16)9~~ After January 1, 2023, cannabis product packaging, logos, and brand names shall be pre-approved by the department.

R68-28-1[4]5. Transportation.

(1) A printed transport manifest shall accompany each transport of cannabis.

(2) The manifest shall contain the following information:

(a) the cannabis production establishment address and license number of the departure location;

(b) physical address and license number of the receiving location;

(c) strain name, quantities by weight, and unique identification numbers of each cannabis material to be transported;

(d) date and time of departure;

(e) estimated date and time of arrival; and

(f) name and signature of each agent accompanying the cannabis.

(3) The transport manifest may not be voided or changed after departing from the original cannabis production establishment.

(4) A copy of the transport manifest shall be given to the receiving cannabis production establishment or medical cannabis pharmacy.

(5) The receiving cannabis processing facility, independent laboratory, or medical cannabis pharmacy shall ensure that the cannabis material received is as described in the transport manifest and shall:

(a) record the amounts received for each strain into the inventory control system; and
(b) document any differences between the quantity specified in the transport manifest and the quantities received in the inventory control system.

(6) During transportation, cannabis shall be:

- (a) shielded from the public view;
- (b) secured; and
- (c) temperature controlled if perishable.

(7) A cannabis production facility shall contact the department within 24 hours if a vehicle transporting cannabis is involved in an accident that involves product loss.

(8) Only the registered agents of the cannabis processing facility may occupy a transporting vehicle.

R68-28-1[5]6. Recall Protocol.

(1) The department may initiate a recall of cannabis or cannabis products if:

- (a) evidence exists that pesticides not approved by the department are present on or in the cannabis or cannabis product;
- (b) evidence exists that residual solvents are present on or in cannabis or cannabis product;
- (c) evidence exists that harmful contaminants are present on or in cannabis or cannabis product; or
- (d) the department believes or has reason to believe the cannabis or cannabis product is unfit for human consumption.

(2) The recall plan of a cannabis processing facility shall include, at a minimum:

- (a) a designation of at least one member of the staff who serves as the recall coordinator;
- (b) procedures for identifying and isolating product to prevent or minimize distribution to patients;
- (c) procedures to retrieve and destroy product; and
- (d) a communications plan to notify those affected by the recall.

(3) The cannabis processing facility shall track the total amount of affected cannabis or cannabis product and the amount of affected cannabis or cannabis product returned to the facility as part of the recall.

(4) The cannabis processing facility shall coordinate the destruction of the cannabis or cannabis product with the department and allow the department to oversee the destruction of the affected product.

(5) The department has authority to monitor the progress of the recall until the department declares an end to the recall.

(6) A cannabis production facility shall notify the department before initiating a voluntary recall.

R68-28-1[6]7. Cannabis Waste Disposal.

(1) Solid and liquid wastes generated during cannabis processing shall be stored, managed, and disposed of in accordance with applicable state law[~~s and regulations~~].

(2) Wastewater generated during the cannabis production and processing shall be disposed of in compliance with applicable state law[~~s and regulations~~].

(3) Cannabis waste generated from the cannabis plant, trim, and leaves is not considered hazardous waste unless it has been treated or contaminated with a solvent[~~;~~] or pesticide.

(4) Cannabis waste shall be [~~rendered~~]made unusable before leaving the cannabis processing facility.

(5) Cannabis waste, [~~which~~]that is not designated as hazardous, shall be [~~rendered~~]made unusable by grinding and incorporating the cannabis waste with other ground materials so the resulting mixture is at least 50% non-cannabis waste by volume or other methods approved by the department before implementation.

(6) Materials used to grind and incorporate with cannabis fall into two categories:

- (a) compostable; or
- (b) non-compostable.

(7) Compostable waste is cannabis waste to be disposed of as compost or in another organic waste method mixed with:

- (a) food waste;
- (b) yard waste; or
- (c) vegetable-based grease or oils.

(8) Non-compostable waste is cannabis waste to be disposed of in a landfill or another disposal method, such as incineration, mixed with:

- (a) paper waste;
- (b) cardboard waste;
- (c) plastic waste; or
- (d) soil.

(9) Cannabis waste includes:

- (a) cannabis plant waste, including roots, stalks, leaves, and stems;
- (b) excess cannabis or cannabis products from any quality assurance testing;
- (c) cannabis or cannabis products that fail to meet testing requirements; and
- (d) cannabis or cannabis products subject to a recall.

R68-28-1[7]8. Change in Operation Plans.

(1) A cannabis processing facility shall submit a notice, on a form provided by the department, before making any changes to the facility's operating plan, including:

- (a) ownership or financial backing of the facility;
- (b) the facility's name;
- (c) a change in location;
- (d) any modification, remodeling, expansion, reduction or physical, non-cosmetic alteration of a facility;[~~or~~]
- (e) change to the number of production lines[~~;~~]; or
- (f) any information requested by the department that shall allow the department to determine if requirements will be met.

(2) A cannabis processing facility may not implement changes to the initial approved operation plan without board approval.

(3) The board shall approve of requested changes unless approval would lead to a violation of the applicable laws and rules of the state.

(4) The department shall specify the reason for the denial of approval for a change to the operation plan.

(5) Before the board's review of a cannabis production establishment license under Subsection 4-41a-201.1(7)(e), the cannabis production establishment shall provide the board with:

(a) blueprints that show that there will be physical separation between medical cannabis and industrial hemp produced in their facility, including demonstrating storage and packaging areas on separate sides of the same room; and

(b) any information requested by the board that shall allow the board to determine if the requirements of Section R68-28-5 will be met before the medical cannabis production establishment processes industrial hemp or industrial hemp products.

R68-28-1[8]9. Renewals.

(1) A cannabis processing facility shall submit a notice of intent to renew and the licensing fee to the department within 30 days of license expiration.

(2) If the licensing fee and intent to renew are not submitted within 30 days of license expiration, the licensee may not continue to operate.

(3) The board may take into consideration significant violations issued in determining license renewals.

R68-28-[19]20. Violation Categories.

(1) Public Safety Violations: \$3,000- \$5,000 per violation. This category is for violations which present a direct threat to public health or safety including:

(a) cannabis sold to an unlicensed source;

(b) cannabis purchased from an unlicensed source;

(c) refusal to allow inspection;

(d) failure to comply with testing requirements;

(e) a test result for high pesticide residue in the cannabis produced or cannabis product;

(f) a test result for high residual solvents, heavy metal, microbials, molds, or other harmful contaminants;

(g) failure to maintain required cleanliness and sanitation standards;

(h) unauthorized personnel on the premises;

(i) permitting criminal conduct on the premises;

(j) possessing, manufacturing, or distributing cannabis products that the person knows or should know appeal to children;

(k) failure to follow an approved recall protocol; or

(l) engaging in or permitting a violation of the Title 4, Chapter 41a, Cannabis Production Establishments, which amounts to a public safety violation as described in this subsection.

(2) Regulatory Violations: \$1,000-\$5,000 per violation. This category is for violations involving this rule and other applicable state rules including:

(a) failure to maintain alarm and security systems;

(b) failure to keep and maintain records for at least two years;

(c) failure to maintain traceability;

(d) failure to follow transportation requirements;

(e) failure to follow the waste and disposal requirements;

(f) failure to maintain separation between cannabis and hemp;

(g) failure to follow labeling and packaging requirements;

(h) failure to meet extraction requirements;

(i) distributing a final cannabis product with an actual weight that is lower than the net weight listed on the cannabis fact panel;

(j) engaging in or permitting a violation of Title 4, Chapter 41a, Cannabis Production Establishments or this rule which amounts to a regulatory violation as described in this subsection; or

(k) failure to maintain standardized scales.

(3) Licensing Violations: \$500- \$5,000 per violation. This category is for violations involving licensing requirements including:

(a) an unauthorized change to the operating plan;

(b) failure to notify the department of changes to the operating plan;

(c) failure to notify the department of changes to financial or voting interests of greater than 2%;

(d) failure to follow the operating plan as approved by the department;

(e) engaging in or permitting a violation of this rule or Title 4, Chapter 41a, Cannabis Production Establishments which amounts to a licensing violation as described in this subsection; or

(f) failure to respond to violations.

(4) The department shall calculate penalties based on the level of violation and the adverse effect or potential adverse effect at the time of the incidents giving rise to the violation.

(5) The department may enhance or reduce the penalty based on the seriousness of the violation.

KEY: cannabis processing, cannabis production establishment

Date of Last Change: [~~October 24, 2022~~]2023

Authorizing, and Implemented or Interpreted Law: 4-41a-103(5); 4-41a-404(3); 4-41a-701(3); 4-41a-302(3)(b)(ii); 4-2-103(1)(i); 4-41a-405(2)(b)(iv); 4-41a-801(1)

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